

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: William M. Hung et al. Examiner: Unassigned
Serial No.: 10/681,560 Group Art Unit: 1772
Filed: October 8, 2003 Docket: 60126.0003US01
Title: WATER-SOLUBLE CHITOSAN HAVING LOW ENDOTOXIN CONCENTRATION AND METHODS FOR MAKING AND USING THE SAME

CERTIFICATE UNDER 37 CFR 1.8:

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail, with sufficient postage, in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on February 2, 2004.

By: _____

Name: Leonard J. Hope

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

23552

PATENT TRADEMARK OFFICE

Sir:

We are transmitting herewith the attached:

- ☒ Transmittal Sheet in duplicate containing Certificate of Mailing
- ☒ Information Disclosure Statement, Form 1449, 36 Reference(s)
- ☒ Return postcard

Please consider this a PETITION FOR EXTENSION OF TIME for a sufficient number of months to enter these papers or any future reply, if appropriate. Please charge any additional fees or credit overpayment to Deposit Account No. 13-2725. A duplicate of this sheet is enclosed.

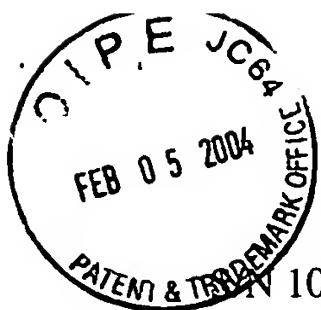
MERCHANT & GOULD LLC
P.O. Box 2903, Minneapolis, MN 55402-0903
404.954.5100

By: _____

Name: Leonard J. Hope

Reg. No.: 44,774

LJH



10/681,560

PATENT

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INFORMATION DISCLOSURE STATEMENT (37 C.F.R. § 1.97(b))

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

With regard to the above-identified application, the items of information listed on the enclosed Form 1449 are brought to the attention of the Examiner.

This statement should be considered because it is submitted before the mailing date of a first Office Action on-the-merits. Accordingly, no fee is due for consideration of the items listed on the enclosed Form 1449.

In accordance with 37 C.F.R. §1.98(a)(2)(i), a copy of the U.S. patents and U.S. patent publications listed on the enclosed Form 1449 are not provided, as this application was filed after June 30, 2003. A copy of any foreign patent document or "Other Document" listed on the Form 1449 is enclosed, in accordance with 37 C.F.R. §1.98(a)(2).

No representation is made that a reference is "prior art" within the meaning of 35 U.S.C. §§ 102 and 103 and Applicants reserve the right, pursuant to 37 C.F.R. § 1.131 or otherwise, to establish that the reference(s) are not "prior art." Moreover, Applicants do not represent that a reference has been thoroughly reviewed or that any relevance of any portion of a reference is intended.

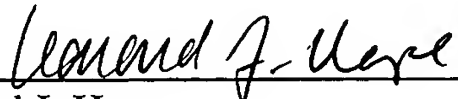
Consideration of the items listed is respectfully requested. Pursuant to the provisions of M.P.E.P. 609, it is requested that the Examiner return a copy of the attached Form 1449, marked as being considered and initialed by the Examiner, to the undersigned with the next official communication.

Please charge any additional fees or credit any overpayment to Deposit Account No. 13-2725.

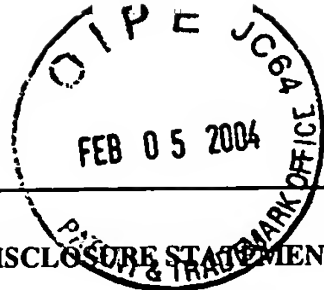
Respectfully Submitted,

Merchant & Gould, LLC




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Minneapolis, Minnesota 55402-0903
Telephone: 404-954-5100



FORM 1449*

INFORMATION DISCLOSURE STATEMENT

IN AN APPLICATION

(Use several sheets if necessary)

Docket Number:

60126.0003US01

Application Number:

10/681,560

Applicant: HUNG ET AL.

Filing Date: 10/08/2003

Group Art Unit: 1772

U.S. PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NO.	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	4,168,112	09/18/1979	Ellis et al.			
	4,259,202	03/31/1981	Tanaka et al.			
	4,826,826	05/02/1989	Conti			
	4,885,168	12/05/1989	Hashimoto et al.			
	4,909,942	03/20/1990	Sato et al.			
	4,979,959	12/25/1990	Guire			
	4,996,307	02/26/1991	Itoi et al.			
	5,057,542	10/15/1991	Leuba et al.			
	5,169,535	12/08/1992	Adachi et al.			
	5,290,813	03/01/1994	Clark et al.			
	5,409,731	04/25/1995	Nakagawa et al.			
	5,422,116	06/06/1995	Yen et al.			
	5,451,237	09/19/1995	Vehige			
	5,520,920	05/28/1996	Castillo et al.			
	5,536,155	07/16/1996	Futaki et al.			
	5,549,919	08/27/1996	Ueno et al.			
	5,589,591	12/31/1996	Lewis			
	5,658,915	08/19/1997	Abe et al.			
	5,891,913	04/06/1999	Sallmann et al.			
	6,284,749	09/04/2001	Castillo et al.			
	6,589,999	07/08/2003	Gurny et al.			

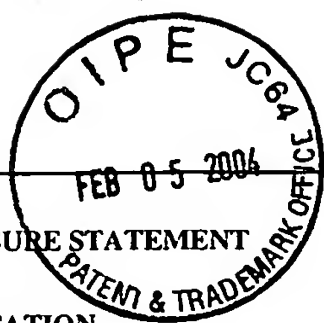
FOREIGN PATENT DOCUMENTS

	DOCUMENT NO.	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
						YES	NO
	1229071	09/22/1999	CN			Abstract Only	
	19857548	08/03/2000	DE			Abstract	

EXAMINER

DATE CONSIDERED

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form for next communication to the Applicant.



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FOREIGN PATENT DOCUMENTS

	DOCUMENT NO.	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
						YES	NO
	63169975 A	08/13/1988	JP			Abstract Only	
	1010970 A	01/13/1989	JP			Abstract Only	
	1050014 A ✓	02/27/1989	JP			Abstract Only	
	1265224 A	10/23/1989	JP			Abstract Only	
	1293314 A ✓	11/27/1989	JP			Abstract Only	
	3102313 A ✓	04/26/1991	JP			Abstract Only	
	5142502 ✓	06/11/1993	JP			Abstract Only	
	6181970 ✓	07/05/1994	JP			Abstract Only	
	7223966 A ✓	08/22/1995	JP			Abstract Only	
	7324014	12/12/1995	JP			Abstract Only	
	WO 94/13774	06/23/1994	PCT				
	WO 96/20730	07/11/1996	PCT				
	WO 97/06782	02/27/1997	PCT				
	WO 99/40790	08/19/1999	PCT				
	WO 00/30609	06/02/2000	PCT				
	WO 02/09513 A2	02/07/2002	PCT				

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

	Application Serial No. 07/986,959, Powell et al., "COMPOSITIONS AND METHODS FOR INHIBITING AND REDUCING LYSOZYME DEPOSITION ON HYDROPHILIC CONTACT LENSES," 27 pgs. (Filed: December 9, 1992).
	Brochure, "Limulus Amebocyte Lysate Endosafe KTA™, U.S. License No. 1197, Multi-Test Vial For Endotoxin (Pyrogen) Detection," Charles River Endosafe, 2 pgs., (Date Unknown).
	Brochure, "Amino acid based surfactant, Amisoft," Munomoto, 6 pgs. (Date Unknown).
	Brochure, "HAMPOSYL N-Acyl Sarcosinate Surfactants," Hampshire, A Subsidiary of The Dow Chemical Company, 30 pgs. (Date Unknown).
	Bough, W. et al., "Influence of Manufacturing Variables on the Characteristics and Effectiveness of Chitosan Products. II. Coagulation of Activated Sludge Suspensions," Biotechnology and Bioengineering, Vol. XX, No. 12, pp. 1945-1955 (December 1978).

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	Applicant: HUNG ET AL.	
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OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)		
		Davydova, V. et al., "Interaction of Bacterial Endotoxins with Chitosan. Effect of Endotoxin Structure, Chitosan Molecular Mass, and Ionic Strength of the Solution on the Formation of the Complex," <i>Biochemistry</i> , Vol. 65, No. 9, pp. 1082-1090 (2000).
		Felt, O. et al., "Topical use of chitosan in ophthalmology: tolerance assessment and evaluation of precorneal retention," <i>International Journal of Pharmaceutics</i> , Vol. 180, pp. 185-193 (1999).
		Felt, O. et al., "Chitosan as Tear Substitute: A Wetting Agent Endowed with Antimicrobial Efficacy," <i>Journal of Ocular Pharmacology And Therapeutics</i> , Vol. 16, No. 3, pp. 261-270 (2000).
		Felt, O. et al., "Delivery of Antibiotics to the Eye Using a Positively Charged Polysaccharide as Vehicle," <i>AAPS Pharmaceutical</i> , http://www.pharmsci.org/scientificjournals/pharmsci/journal/01_34.html , Article 34, 9 pgs. (2001).
		Hirano, S. et al., "Selective <i>N</i> -acylation of chitosan*," <i>Carbohydrate Research</i> , Vol. 47, pp. 315-320 (1976).
		Kristiansen, A. et al., "The interactions between highly de- <i>N</i> -acetylated chitosans and lysozyme from chicken egg white studied by ¹ H-NMR spectroscopy," <i>Eur. J. Biochem.</i> , Vol. 251, pp. 335-342 (1997).
		Kristiansen, A. et al., "Competitive binding of highly de- <i>N</i> -acetylated chitosans and <i>N,N'</i> -diacetylchitobiose to lysozyme from chicken egg white studied by ¹ H NMR spectroscopy," <i>Carbohydrate Research</i> , Vol. 289, pp. 143-150 (1996).
		Kurita, K. et al., "Studies on Chitin, 3*), Preparation of Pure Chitin, Poly(<i>N</i> -acetyl-D-glucosamine), from the Water-Soluble Chitin," <i>Makromol. Chem.</i> , Vol. 178, pp. 2595-2602 (1977).
		Kurita, K. et al., "Solubilization of a Rigid Polysaccharide: Controlled Partial <i>N</i> -Acetylation of Chitosan to Develop Solubility," <i>Carbohydrate Polymers</i> , Vol. 16, pp. 83-92 (1991).
		LeHoux, J. et al., "Some Effects of Chitosan on Liver Function in the Rat*," <i>Endocrinology</i> , Vol. 132, No. 3, pp. 1078-1084 (1993).
		Sannan, T. et al., "Studies on Chitin, 2*), Effect of Deacetylation on Solubility," <i>Makromol. Chem.</i> , Vol. 177, pp. 3589-3600 (1976).
		Schorigin, P. et al., "Über die Acetylierung des Chitins (Vorläufig. Mitteil.)," <i>Aus. d. Organ. Laborat. d. Wissenschaftl. Instituts für Kunstseide, Moskau</i> , 3 pgs. (1935).
		Wu, A. et al., "Influence of Manufacturing Variables on the Characteristics and Effectiveness of Chitosan Products. III. Coagulation of Cheese Whey Solids," <i>Biotechnology and Bioengineering</i> , Vol. XX, No. 12, pp. 1957-1966 (December 1978).

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